DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

"DISCUSSION DRAFT OF THE 'FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT' LEGISLATION: DEVICE AND COSMETICS SAFETY"

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Stephen F. Sundlof, D.V.M., Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA or the Agency). With me today is Lillian Gill, D.P.A., Senior Associate Director, Center for Devices and Radiological Health. Thank you for the opportunity to discuss FDA's progress in responding to the challenges created by medical devices for the United States (U.S.) market that are either fully manufactured overseas or that are manufactured in the U.S. but contain foreign components. We also appreciate your interest in FDA's cosmetics program by including it as an additional topic of this hearing. FDA's mission is to ensure that products available in the U.S. meet appropriate standards for safety and, for medical products, effectiveness, regardless of where they are produced. In my testimony today, I will outline activities the Agency is undertaking to accomplish this goal.

COSMETICS

Let me first provide some background regarding FDA's cosmetics program. Every day across the country, Americans use a wide variety of cosmetic products, including skin moisturizers, shampoos, perfumes, lipsticks, nail polishes, eye and face make-up, hair colors and deodorants. These consumers expect their cosmetics – and the wide variety of individual ingredients in their cosmetics – to be safe. The FDA's oversight has ensured that the Nation's cosmetics are among the safest in the world.

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. In general, except for color additives and those

ingredients which are prohibited or restricted from use in cosmetics by regulation[1], a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled. FDA regulations also specify the labeling requirements for cosmetics, including warning statements on the labels of certain types of cosmetics such as coal tar hair dyes. If manufacturers do not remove dangerous products from the market, the Agency can pursue enforcement actions against violative products or against firms or individuals who violate the law.

Cosmetic manufacturers are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing and packaging) of establishments that participate in this program. FDA uses the registration to estimate the size of the cosmetic industry and for conducting on-site establishment inspections. Information from the VCRP database assists the Cosmetic Ingredient Review Expert Panel in determining its priorities for ingredient safety review. Currently, 972 domestic and 612 foreign cosmetic manufacturing establishments are registered with FDA. Though the mix of cosmetic products sold to U.S. consumers is constantly changing, we estimate that the registration system contains product information from a third of all domestic manufacturers.

[1] FDA regulations specifically prohibit or restrict the use of ten types of ingredients in cosmetic products due to safety concerns. 21CFR700Subpart B

Though we believe cosmetics sold in the U.S. are safe, we recognize that the cosmetics industry is expanding and changing. During the past five to ten years, Americans have seen an explosion in the numbers and types of cosmetic products sold annually. The domestic cosmetic industry has annual U.S. sales which are now exceeding $62 billion. To meet demand, cosmetic products and ingredients are also entering the U.S. from a growing number of countries. Though manufacturers are required to ensure the safety of products sold in the U.S., the regulatory systems and standards in many countries are different from those of the U.S. and often from each other. In 2007, cosmetic products and ingredients accounted for nine percent (9%) of all imports under FDA's jurisdiction. From 2000 to 2007, the number of these import entries more than tripled. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue. To address the increasing need for coordination, FDA and its counterparts in the European Union, Canada, and Japan have established a new forum for cooperation and communication on issues of common concern in the cosmetics arena, known as International Cooperation on Cosmetics Regulation.

In addition, the cosmetics industry is rapidly undergoing significant changes as the technologies used in manufacture become increasingly sophisticated and the ingredients, more complex. For example, products that straddle the line between cosmetics and drugs also present new challenges. The industry often refers to these products as "cosmeceuticals," a term which has no legal or regulatory definition in the U.S. Many products in this category are advertised as containing "active ingredients," which are ingredients sometimes used in pharmaceuticals. We note that any product that purports

to treat, cure, or prevent disease (i.e., making a drug claim) would be considered a drug and would need to obtain FDA drug approval. However, we recognize that the use of such ingredients is increasing and we expect this trend to continue. For example, retinol, an ingredient used in cosmetic anti-wrinkle preparations (as well as over-the-counter drug preparations), was not listed in any cosmetic product ingredient statement in FDA's VCRP database in 2003; by 2006 it was listed in almost 50. It is currently listed in 163 cosmetic product ingredient statements. Peptides, a class of cosmetic ingredient also used in skin care preparations and associated with certain drug-like product claims, were not listed in any cosmetic product ingredient statements filed with FDA prior to 2005. Currently, there are over 40 different peptides listed in over 500 cosmetic product ingredient statements.

FDA is committed to ensuring the safety of cosmetics used by consumers across the U.S. FDA will continue to work closely with all of its partners, including international regulatory authorities, on a wide variety of issues important in cosmetic safety, including ingredient usage and labeling, market surveillance, and areas of emerging science.

MEDICAL DEVICES

Foreign-manufactured medical devices must meet FDA regulatory requirements in order to be imported into the U.S. or its territories. These requirements include establishment registration, device listing, manufacturing in accordance with the Quality System Regulation, reporting of adverse events, and Pre-market Notification 510(k) or

Pre-market Approval, if applicable. Foreign manufacturers must also designate a U.S. agent. The responsibilities of the U.S. agent include assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign establishment's devices that are imported or offered for import, assisting FDA in scheduling inspections of the foreign establishment and, if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, which is considered equivalent to providing the same information or documents to the foreign establishment. FDA inspects foreign manufacturing sites to help assess compliance with FDA requirements and to help inform decisions regarding admissibility of products into U.S. commerce. Initial importers also must register with FDA. An initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the consumer.

FDA works cooperatively with Customs and Border Protection (CBP) in regulating imported FDA-regulated products. Products that do not meet FDA regulatory requirements may be detained at the border.

Our existing authorities help ensure the safety and effectiveness of medical devices manufactured in foreign establishments and intended for use in the U.S. In addition, FDA has many initiatives underway to further protect and promote the public health under the auspices of the Administration's Action Plan for Import Safety.

ACTION PLAN FOR IMPORT SAFETY

As you know, last year, President Bush issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products, and asked Secretary Leavitt to lead the group. The working group, which includes representatives from twelve Federal departments and agencies, reviewed the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the "Action Plan for Import Safety" to the President. This Action Plan presents broad recommendations and specific short- and long-term action steps, categorized under the organizing principles of prevention, intervention, and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. That report concluded that the U.S. must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important phases. In the Action Plan, we identified several new legislative authorities that are needed to do this.

Prevention

FDA is seeking to ensure that imported devices are safe and effective and meet all applicable FDA standards *prior* to reaching U.S. ports-of-entry. FDA is pursuing this goal through the following key efforts.

Maximizing Foreign Medical Product Pre-Approval Inspections. Prior to the approval of a medical device pre-market approval application, FDA must determine that the firm's manufacturing processes are adequate to consistently produce a safe and effective device.

Each year, FDA performs foreign device pre-approval inspections which assess data in applications and a firm's GMP compliance. These inspections are designed to evaluate the capability of manufacturing facilities to generate a safe and high-quality product and address manufacturing location, design, source and specifications of components, manufacturing controls, and product labeling and servicing, among other things. FDA conducted more total foreign inspections in Fiscal Year (FY) 2007 than at any other time in the Agency's history. In FY 2007, FDA conducted 289 inspections of foreign device manufacturers, compared to 233 in FY 2005, and 219 in FY 2006. We plan to conduct 392 foreign device manufacturer inspections in FY 2009. It is critical to note, however, that while inspections are an important component to ensuring the safety of imported medical products, simply calling for more inspections is not the solution.

Beyond Our Borders Initiative. The FDA Beyond Our Borders Initiative is a multi-pronged approach to promote and verify compliance of imported food, cosmetics, and medical products with FDA requirements. This Initiative includes increased FDA presence overseas, increased FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party certification, and increased capacity building with countries that have less developed regulatory systems to ensure product safety.

Foreign Presence. China is one of the largest exporters of medical products for the U.S. market. Recently, FDA and Department of Health and Human Services leadership, the Department of State, and the U.S. Ambassador to China committed to establishing an FDA office in China this year**.** On March 8, 2008, the Department of State approved FDA to place 13 total staff in China (eight FDA personnel and five Foreign Nationals). This staff will be responsible for building closer working relationships with our Chinese counterparts, carrying out inspections, and working with Chinese inspectors to provide training. FDA is in the process of making the necessary arrangements and preparing to hire staff. This effort builds on two recently-signed Memoranda of Agreements (MoA) with FDA counterparts. One of the agreements with China's State Food and Drug Administration (SFDA) pertains to medical products, including devices. This MoA will improve regulatory cooperation and information sharing concerning medical products exported from China to the U.S. Starting with products designated in the agreement, SFDA will require registration for products exported to the U.S. and will eventually be able to certify that FDA standards are met for those products. Under the MoA, SFDA is required to respond promptly to information requests about medical products and promptly notify FDA of any serious adverse health consequences associated with Chinese medical products shipped to the U.S. In addition, SFDA will notify FDA of significant non-compliance, including counterfeiting. Furthermore, the agreement provides for a streamlined process for facilitating FDA inspections conducted in China. This aspect of the agreement has already proven effective in gaining FDA prompt access to conduct inspections involving Chinese heparin. This is a significant step toward ensuring the safety and efficacy of medical products produced for the U.S. market.

FDA's efforts will build stronger cooperative relationships with counterpart agencies in China, enhance technical cooperation with these agencies, and foster the flow of information between regulatory systems. Having an overseas presence in China will improve our ability to inspect facilities in China and, very importantly, foster greater interactions between FDA staff and Chinese manufacturers to help ensure that products shipped to the U.S. meet FDA standards for safety and manufacturing quality. In addition, FDA is working to establish beneficial collaborations with India, another large exporter of medical products to the U.S.

Ramping Up Field Efforts. To meet the challenges posed by the increase in the globalization of U.S. drug and device development, FDA must significantly strengthen its field and international inspection operations. Goals for FY 2009 include increasing foreign and domestic inspections and sampling, improving our laboratory infrastructures, continuing to develop tools for rapid analysis, and, as previously mentioned, establishing an in-country presence in China.

Sharing Foreign Inspection Reports. FDA now has over 30 confidentiality arrangements with foreign counterparts, many of which provide mechanisms for sharing inspection reports. FDA intends to increase the use of these arrangements to obtain useful information that can help the Agency make more informed judgments about the safety of foreign-sourced products, in prioritizing our foreign inspection activities, and on detaining unsafe products.

Providing for Certification by Third Parties. As recommended in the President's Action Plan for Import Safety, FDA is pursuing the use of voluntary third party certification to

verify compliance with FDA requirements. These third parties may include foreign government agencies and independent entities who have been accredited by FDA or accreditation organizations recognized by FDA. With proper structuring to stimulate the use of third party certification, this certification would complement, but not supplant, FDA inspectional and other regulatory activities.

Providing Technical Assistance. Another essential element of the Agency Beyond Our Borders Initiative focuses on helping foreign regulators understand FDA standards, laws and regulations by providing technical assistance to counterpart foreign regulators and outreach assistance to foreign industries that engage in trade with the U.S.

Intervention

FDA recognizes the importance of a strong and effective intervention capacity to identify problems as they occur.

Information Technology (IT). FDA has several plans to enhance its IT systems in ways that will enable the Agency to better utilize risk-based information throughout the life-cycle of imported products. These projects will improve databases, enhance interoperability of systems within the Agency and among other regulatory agencies, and provide better analytical function to assess and control risk. We expect these improvements will help to target our intervention efforts related to foreign firms.

Expanding Laboratory Capacity & Development of Rapid Test Methods. FDA must be agile and scientifically sophisticated, with the ability to develop rapid test methods for detection of pathogens and other contaminants in products, and to ensure that these test

methods are available at ports-of-entry to assist in determining whether a product should be admitted into the U.S. FDA research laboratories develop and validate methods, such as the test FDA developed to determine the contaminant in heparin ingredients imported from China. This novel testing method is now accepted and used worldwide to detect the presence of hypersulfated chondroitin sulfate in heparin.

Prioritizing Surveillance Inspections. In addition to pre-approval inspections, FDA conducts surveillance inspections of domestic and foreign manufacturers and uses a risk-based priority model to determine which facilities may pose a risk to the American consumer. FDA staff must consider a number of elements in making a risk-based priority determination, including: the class of device, the date the facility was last inspected, the compliance history of the firm, the firm's shipping volume and history, and information from the local regulatory authorities regarding the manufacturing quality and regulatory status of the establishment.

Response

When a health threat emerges with any FDA-regulated product, whether manufactured domestically or abroad, FDA must be ready to take immediate action.

Making the Border an Integrated Checkpoint. The Action Plan for Import Safety calls for increased FDA and CBP cooperation, including the development of interdepartmental procedures for clearing and controlling shipments at ports-of-entry, co-locating FDA and CBP at locations to improve coordination and efficient use of resources, and greater import information sharing between FDA and CBP through new technology applications.

Rapid Deployment of "For Cause" Inspections. When FDA has information that raises doubts about the safety of a regulated product, it will rapidly conduct domestic or foreign "for cause" inspections. In such cases, the Agency targets a particular firm or product as an inspection priority based on this information and rapidly deploys an inspection team.

Expanded Use of Track-and-Trace Technologies. FDA is working to facilitate the adoption by industry of track-and-trace technologies to identify and track a product along the product's life-cycle. These technologies will facilitate the timely recovery of the violative product and reduce the opportunity for harm, as well as secure the integrity of the supply**.** The use of track-and-trace technologies provides important life-cycle information back to the point-of-origin. Under the Food and Drug Administration Amendments Act of 2007, FDA is working to develop or recognize unique identifiers which may support product identification technologies.

NEW AUTHORITIES

The Action Plan for Import Safety called for providing a number of new authorities in order to enhance the safety of imported products. It requests authority to establish mandatory import certification programs -- using accredited third parties (which could include federal departments, foreign governments, or private entities) – that are based on product risk to verify compliance with U.S. safety standards. As appropriate, mandatory import certification would include periodic on-site inspections, random testing and certification renewal based on product risk. Product certification could be mandatory for certain high-risk products coming from countries with which the U.S. has entered into agreements. Under the agreements, the countries or accredited third-parties would

certify products as meeting U.S. standards prior to their export to the U.S. Such a procedure would be limited to high-risk products that have been shown to pose a threat to public health.

Additionally, the plan recommends authorizing FDA to refuse admission of a foreign manufacturer's product when FDA encounters undue delay, limits, or denials of access to the foreign manufacturing sites where the product was produced. At present, foreign firms can often deny inspectors access to their facilities without any adverse consequence. The plan also requests authority to expedite destruction of refused medical products, which will prevent unsafe medical products for personal use from entering the U.S. market. Finally, amending the FD&C Act to include asset forfeiture remedies for certain criminal offenses would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used to aid in the importing, exporting, transporting, selling, receiving, acquiring and purchasing of violative products by those who knowingly and willingly violate the Act.

FDA GLOBALIZATION ACT OF 2008

We commend the Members of this Subcommittee and their staffs for developing the discussion draft entitled, the "Food and Drug Administration Globalization Act of 2008." We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety.

We are in the process of reviewing the discussion draft in detail and we look forward to working with you on this legislation. At this time we can, however, describe some general principles that guided the development of the Action Plan for Import Safety

which we believe should also guide the development of product safety legislation.

- Any legislation should move to a more risk-based, cost-effective approach to identify and mitigate risks posed by imported products.
- Given the breadth and scope of products imported into the U.S., as well as those produced domestically, FDA cannot rely on inspection as its primary means of ensuring product safety. Any legislation should build on the framework in the Action Plan for Import Safety, i.e., building in safety measures to address risks throughout a product's life cycle and focus efforts on preventing problems first, and then using risk-based interventions to ensure preventive approaches are effective, coupled with a rapid response as soon as a problem is detected.
- While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance and efforts or programs designed to recoup the costs of regulatory actions resulting from findings of violations (such as reinspections), the Administration will carefully review any proposed user fee program to ensure that it is being assessed against identifiable recipients of special benefits derived from Federal activities beyond those received by the general public.
- Any legislation should be carefully designed to avoid creating real or perceived trade barriers, and several provisions of the bill may need to be reviewed in light of U.S. trade agreement obligations. We are reaching out to the U.S. Trade Representative for further insight on these.
- Any legislation should empower robust voluntary private sector efforts already underway.

With these in mind, we believe the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections appear not to be sufficiently focused on high-risk products. Some of these requirements would divert resources, which could detract from important product safety and security priorities. In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging third party certification and efforts by foreign nations already underway.

CONCLUSION

As you can see, efforts are underway at FDA to ensure that products are safe and medical products are safe and effective regardless of where they are manufactured. We share your interest in enhancing the safety of imported products and look forward to continuing to work with Members and staff on the Committee and Subcommittee. We also look forward to working with you on the Action Plan for Import Safety. Thank you for the opportunity to testify today, and we are happy to respond to any questions you may have.